

CLAIMS

1. A process for production of cation crystals of GH or of GH derivatives, comprising the following steps:

- a) to a solution of GH or derivatives thereof is added 5 cations of inorganic or organic nature and an organic solvent or a mixture of organic solvents at a pH between 5.0 and 6.8,
- b) growing of crystals at a temperature from about 0 to about 30°C, and
- c) isolation of the cation crystals by known means.

10 2. A process according to claim 1, wherein the pH in step a) is from 5.8 to 6.5, preferably from 6.0 to 6.5.

3. A process according to claim 1, wherein the organic solvent is selected from the group consisting of short chained aliphatic, cyclic or aromatic alcohols or ketones.

15 4. A process according to claim 3, wherein the organic solvent is selected from the group consisting of acetone, methanol, ethanol and 2-propanol.

5. A process according to claim 4, wherein the organic solvent is ethanol or acetone.

20 6. A process according to any of claims 1 to 5 wherein the organic solvent is added in a concentration of about 0.1 to about 50% v/v.

7. A process according to claim 6, wherein the organic solvent is added in a concentration of 0.1 to 30%, preferably from 0.1 to 25% to 20%, more preferred from 5 to 15% and most preferred from 6 to 12%.

8. A process according to any of the preceding claims 1 to 7, wherein the cation is a divalent cation.

9. A process according to claim 8, wherein the divalent cation is Zn^{++} .

5 10. A process according to claim 9, wherein Zn^{++} is added in a concentration below the limit for unspecific precipitation of amorphous material.

11. A process according to claim 10, wherein Zn^{++} is added in a concentration from 0.5 to 10 mol $Zn^{++}/mol GH$.

10 12. A process according to claim 11 wherein the concentration of Zn^{++} is from 1.0 to 3.0 mol $Zn^{++}/mol GH$, more preferred from 1.1 to 2.2 mol $Zn^{++}/mol GH$ and most preferred from 1.2 to 2.0 mol $Zn^{++}/mol GH$.

13. A process according to any of the preceding claims, wherein 15 the growth hormone is hGH or derivatives thereof.

14. A process according to any of the preceding claims, wherein the temperature in step b) is from about 4 to about 25°C.

15. Cation crystals of hGH or hGH derivatives.

16. Crystals according to claim 15, wherein the cation is Zn^{++} .

20 17. Crystals according to claim 16, wherein the molar ratio between Zn^{++} and GH is from about 0.2 to about 10, preferably from about 0.5 to 5 and more preferably from about 0.5 to 2.0.

18. Pharmaceutical preparations, characterized in that they contain crystals according to any of claims 15 to 17.

19. Use of a crystallization process according to claims 1 to 14 as a purification and/or isolation step in the manufacturing
of GH.